

KURT R. WHARTON, MD, Inc.

GYNECOLOGY • INFERTILITY • OBESTETRICS • INCONTINENCE

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joel S. Hochman, et al

Set. No.: 10/007.393

Filed: October 26, 2001

For: SYSTEM AND METHOD FOR TRANSDUCING, SENSING  
OR, AFFECTING VAGINAL OR BODY CONDITIONS  
AND/OR STIMULATING PERINEAL MUSCULATURE AND  
NERVES USING 2-WAY WIRELESS COMMUNICATIONS

Examiner: Charles A, Marmon

Group: 3736

Commissioner for  
Patents PO Box 1450  
Alexandria VA 22313

DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUIUCE  
PATENT

I, Kurt R. Wharton MD, declare as follows:

1. I received an A.B. Degree in Physiology and Anatomy from the University of California at Berkeley in 1980. I received my Medical Degree from Boston University School of Medicine in 1984. After completing an Internship in Obstetrics and Gynecology at Mount Zion Hospital and Medical Center in 1985, I was a Resident in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco from 1985 through 1987. I served as Administrative Chief Resident during the academic year ending in 1988. I am currently Chairman, Department of Obstetrics and Gynecology at Alta Bates Summit Hospital in Berkeley, California. Additionally, I am the Site Director for Resident Education and I hold the Academic position of Associate Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. I am a Fellow of the American College of Obstetrics and Gynecology and I am Board Certified by the American Board of Obstetrics and Gynecology.

970 Dewing Ave., Suite #201 • Lafayette, CA 94549  
Phone: 925-962-0002 • Fax: 925-962-0003

S/N 10/007,393  
Amendment dated Sept 29, 2005  
Office Action dated July 13, 2005  
Exhibit 8

2. I am familiar with the subject matter of the above-identified application. Additionally, I have reviewed the U.S. Patent Publication 2002/0010390, Guice, et al.

Based upon my training and professional expertise in Human Physiology, Obstetrics, Gynecology and Women's Health, I can state that no consideration would be given to the Guice Patent by individuals attempting to develop biomedical systems intended to transduce vaginal conditions, affect vaginal or body conditions, or stimulate perineal neuromuscular tissues in humans.

3. By recognized clinical medical standards, the Guice Patent is a Patent for an implant. The Patent clearly identifies telesensor implant units intended for implantation in the ear, vagina, rectum, throat, nostril or subcutaneous tissues of an animal. The telesensors may also be implanted percutaneously. To be explicit, implants are devices surgically placed within or through tissues. Examples of human implants include the Norplant Contraceptive Devices and Cardiac Pacemakers. Human implants require surgical placement and removal. Paragraph 0164 of the Guice Patent states "the telesensor implant, which may be exposed to animal tissue or fluids, should be biocompatible, and in many cases, should promote the ingrowth of tissue to help anchor the telesensor implant in the desired implant location." Obviously, such a device is unacceptable and inappropriate for the human vagina, and in particular could not be self-applied or self-inserted by a human subject.
4. Examples of intravaginal medical devices that are not implants, i.e. are non-implanted devices, include contraceptive diaphragms, pessaries used to treat genital organ prolapse, and medical delivery systems such as the contraceptive NuvaRing and the estrogen releasing Estring. Such devices are placed into the vagina by the patient or healthcare provider and easily removed by the patient or healthcare provider. No surgery, tools or adhesives are required. The Patent requested by Athena allows for the development of temporarily insertable medical devices. These devices are in no way comparable to the Guice implant device.
5. In summary, the Guice implant device is in no way appropriate or acceptable for use in the human vagina. Individuals of ordinary skill in the art developing medical devices for temporary placement, i.e. application or insertion, within the human vagina would not consider the Guice reference.

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6. I hereby declare that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so make are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.

  
Kurt R. Wharton MD

8/24/06  
Date